Opening Statement of Chairman Greg Walden
Subcommittee on Health
Hearing on "Examining Improvements to the Regulation of Medical Technologies"
May 2, 2017

(As prepared for delivery)

Thank you, Chairman Burgess.

We meet today to once again discuss the FDA's vitally important user fee programs. Throughout the hearings we've held examining them this year, I have reiterated the full committee's support of a timely reauthorization of these programs. The good news is that we are well on our way.

To date, the Health Subcommittee held hearings on each of the proposed agreements that were initially submitted to Congress in January. Since that time, we have translated those agreements into legislative language that the committee released with the Senate HELP Committee last month.

As part of that announcement, I noted that we will continue discussions in the House on other member priorities that could strengthen this important legislation.

Today's hearing is a great opportunity for us to learn more about four bipartisan medical device bills that could potentially be included in that effort.

H.R. 1652, the Over-the-Counter Hearing Aid Act, introduced by Reps. Kennedy, Carter, and Blackburn would require FDA to issue regulations establishing a category of OTC hearing aids for adults with perceived mild to moderate hearing loss. Both the President's Council of Advisors on Science and Technology and the National Academies have called for this approach. I understand that some patient safety concerns have been raised and I appreciate the testimony of the FDA and our witnesses on this matter.

H.R. 2118, the Medical Device Servicing and Accountability Act, introduced by Reps. Costello and Peters, would require both original medical equipment manufacturers and third-party service providers to register with the FDA and submit adverse event reports. Several small businesses have raised concerns about the costs they would incur in registering. I am committed to ensuring patient

safety while minimizing regulatory burden and look forward to learning more about this bill going forward.

H.R. 2009, the Fostering Innovation in Medical Imaging Act, also introduced by Reps. Costello and Peters would clarify FDA's regulation of imaging devices and contrast agents. This bill includes common-sense changes that would streamline the regulatory review of these important technologies.

Last but not least, Reps. Buschon, Brooks, Peters, and Butterfield have introduced H.R. 1736, which would improve FDA's risk-based approach for inspecting medical device manufacturing facilities both domestically and abroad.

I look forward to discussing these bills further, and would like to thank all of our witnesses for their testimony today. I yield back the balance of my time.